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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,068	09/19/2003	Frank Buettner	I/1399	7677
28501	7590	11/15/2004	EXAMINER	
BOEHRINGER INGELHEIM CORPORATION 900 RIDGEURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877			DAVIS, BRIAN J	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/666,068	BUETTNER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Brian J. Davis	1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 is/are rejected.
- 7) Claim(s) 10-16 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date: _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/9/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by ZA 6802425 (CAPLUS abstract). The reference teaches applicant's compounds when R<sup>1</sup>=R<sup>2</sup>=Me and R<sup>3</sup>=mono substituted (with phenyl or 4-methylphenyl) C<sub>1</sub> alkyl formulated as tablets (a pharmaceutical composition containing an excipient): RN=24008-01-3 and RN=24008-02-4. Claim 9 is included in this rejection as its limitation is intrinsic to the prior art compound. Claims are unpatentable where the prior art process per se of applying the chemical is the same, notwithstanding applicant's different purpose for application of the compound. *In re Kirby*, 40 USPQ 368. This is so because a compound and its properties are inseparable. *In re Papesch*, 315, F.2d 381, 137 USPQ 43 (CCPA 1963).

Claims 1, 8 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 3,567,244, cited by the applicant in the IDS. As outlined above, the reference clearly anticipates the claims because it teaches applicant's compound (example 12 column 11 line 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over ZA 6802425 (CAPLUS abstract)

Applicant claims a set of compounds defined by formula I. The dependent claims further narrow the set.

ZA 6802425 teaches an adjacent homolog of applicant's compound when  $R^1=R^2=R^3=Me$ . That prior art compound is RN=24007-97-4 and is formulated as a tablet (a pharmaceutical composition containing an excipient). Adjacent homologs are considered to be obvious absent unexpected results. "Presumption of unpatentability arises against [a] claim directed to [a] composition of matter the adjacent homologue of which is old in [the] art; burden is on applicant to rebut presumption by showing that [the] claimed compound possess unobvious or unexpected beneficial properties not actually possessed by [the] prior art homologue; it is immaterial that [the] prior art homologue may not be recognized or known to be useful for [the] same purpose or to posses [the] same properties as [the] claimed compound...". This is so because: "[C]haracteristics normally possessed by members of homologous series are principally the same, and vary but gradually from member to member; chemists knowing properties of one member [of the] series would in general know what to expect of adjacent members." *In re Henze*, 85 USPQ 261, 263 (CCPA 1950). Members of a homologous series must possess unexpected properties not possessed by the homologous compounds disclosed in the prior art. *In re Hass*, 141 F.2d 127, 60 USPQ 548 (CCPA 1980).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,657,244.

Applicant's claims have been outlined above.

As outlined above, US 3,657,244 teaches, inter alia, an adjacent homolog of applicant's compound when  $R^1=R^2=R^3=Me$  (example 14 column 11 line 65).

***Allowable Subject Matter***

Claims 10-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**BRIAN DAVIS**  
**PRIMARY EXAMINER**

Brian J. Davis  
November 10, 2004